2 510(k) Summary

[As required by 21 CFR 807.92]

510(k) Number: K120707 **Date Prepared: March 7, 2012**

Submitter's Information / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration Number: 2134812

Contact Person
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Senior Regulatory Product Specialist
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General Information

Trade Name	Switch-It™ catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 870.1250, Percutaneous catheter
Predicate Devices	GuideLiner® V2 catheter (K112082 - Vascular Solutions, Inc.) SuperCross™ microcatheter (K101659 – Vascular Solutions, Inc.)

Device Description

The Switch-It catheter (Switch-It) is an addition to the VSI guide extension catheter product family. Switch-It is a rapid-exchange catheter intended for use with a standard 6F guide catheter to place and exchange standard length 0.014" guidewires. The working length of Switch-It is 145 cm, consisting of a 117 cm proximal stainless steel push wire attached to a 28 cm microcatheter-type shaft. The push wire and shaft are joined by a short funnel section that directs a proximally inserted guidewire into the shaft. The inner diameter of the shaft is sized to accommodate an 0.014" guidewire. The distal 20 cm of the shaft has a hydrophilic coating and a platinum-iridium marker band located 2 mm or less from the distal tip, which is visible using standard fluoroscopic methods. The push wire has two positioning marks located at 95 cm (single mark) and 105 cm (double mark) from the distal tip, respectively.

Intended Use / Indications

The Switch-It catheter is intended to be used in conjunction with guide catheters to facilitate placement and exchange of guidewires in the discrete coronary and peripheral vasculature.

Substantial Equivalence and Summary of Studies

Switch-It is substantially equivalent to the GuideLiner V2 catheter (GuideLiner V2) based on comparisons of intended use, device functionality, and technological characteristics. In addition, the intended use, microcatheter-like design, and materials of Switch-It are similar to the SuperCross microcatheter (SuperCross).

Switch-It and the predicate devices are intended to be used in the coronary and peripheral vasculature to facilitate placement and exchange guidewires. The predicate devices are intended to facilitate placement and exchange of guidewires and other interventional devices; however, the smaller ID of Switch-It allows only the passage of guidewires, not interventional devices. The Switch-It intended use is a subset of the GuideLiner V2 and SuperCross indications, as Switch-It is only indicated to facilitate placement and exchange of guidewires and not other interventional devices.

The Switch-It design was qualified through the following tests:

- Simulated anatomy/concomitant device use
- Kink
- Tensile
- Torque
- Dimensional verification

Results of the verification testing did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

MAY 15 2012

Vascular Solutions, Inc.
c/o Ms. Ellie Gillespie
Senior Regulatory Product Specialist
6464 Sycamore Court
Minneapolis, MN 55369

Re: K120707
Switch-It™ Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 7, 2012
Received: March 8, 2012

Dear Ms. Gillespie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120707

Device Name: Switch-It™ catheter

Indications for Use:

The Switch-It catheter is intended to be used in conjunction with guide catheters to facilitate placement and exchange of guidewires in the discrete coronary and peripheral vasculature.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120707